EXHIBIT 25

EXPERT REPORT

MARTHA M. BENNETT

1. Qualifications and Background

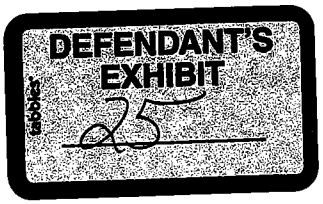
1.1. My name is Martha M. Bennett and I make this disclosure as an individual on behalf of, and in conjunction with, the above-captioned litigation.

1.2. Currently, I am President of Bennett and Company, a consulting firm which I established in 1985 to provide FDA related consulting services to pharmaceutical, biologics, medical device, food, and cosmetic companies. My office address is 107 S. West Street, Alexandria, Virginia 22314.

1.3. I have been retained by attorneys representing Actavis Totowa LLC (Actavis).

1.4. I graduated from the University of Tennessee in 1972 with a Bachelor of Science degree concentrated in the fields of zoology and chemistry. Subsequently, I successfully completed significant course work in various scientific and technical fields, as described in my curriculum vitae attached as Exhibit 1. The selection of course work was based on the need for specific knowledge related to work assignments, rather than pursuit of advanced degrees. As part of my job I am in a continual learning process. I stay current with the technical and regulatory aspects of my consulting career through regular review of scientific and technical materials, FDA laws, regulations, guidelines, and enforcement policies, as well as through my clients.

1.5. I have extensive experience in Food and Drug regulatory matters. I worked at the Food and Drug Administration (FDA) for thirteen years from 1972 to 1985. During that time, I was a field investigator responsible for inspecting manufacturers of pharmaceutical and other products regulated by the agency in order to assess their compliance with current good manufacturing practices and other FDA requirements. In 1977, I became a compliance officer in the agency's Center for Drug Evaluation and Research. In that capacity I participated in the writing of regulations pertaining to the approval of new drugs, post-approval reporting requirements, and current good manufacturing practices (CGMP). I prepared some of the agency's injunction and prosecution cases that resulted from evidence that companies had violated FDA laws and regulations. I worked with colleagues in the agency's Center for Devices and Radiological Health, Office of Chief Counsel, and Office of Regulatory Affairs on regulatory matters involving drugs and medical devices. I also worked with attorneys in the Justice Department and U.S.



Attorneys offices on FDA-related litigation. My final position in FDA began in 1982 as a supervisory policy analyst in the immediate office of the FDA Commissioner. My staff and I were responsible for providing direct support to the Commissioner and FDA's Policy Board in their decision-making process that affected all products regulated by the agency. I worked with staff from various congressional committees and the White House as part of their responsibilities of oversight and development of FDA legislation.

1.6. In 1985, I resigned from FDA to start my consulting business. As a consultant I have conducted several hundred inspections of domestic and foreign facilities that manufacture pharmaceuticals (finished dosage forms and active pharmaceutical ingredients), as well as other products regulated by the FDA. I have taught and lectured extensively on FDA regulatory requirements. I have assisted numerous pharmaceutical clients in complying with regulatory requirements and CGMP at all stages of the life cycle of products, including preparing and reviewing product clearance (marketing) submissions, identifying weaknesses in regulatory and quality systems, and establishing corrective action plans to prevent regulatory problems with FDA. I have taught classes on validation, written a "how-to" manual on validation requirements, and reviewed hundreds of validation protocols and reports for regulated products. I have assisted companies in their investigation and resolution of manufacturing problems, customer complaints, out-of-norm, and out-of-specification test results.

1.7. I maintain my board certification in Regulatory Affairs, initially awarded in 1991. This certification is sponsored by the Regulatory Affairs Professionals Society (RAPS), an international organization of more than 12,000 members, dedicated to the ongoing education of FDA regulatory professionals. The certification process involves an independent review of experience, a written test, and demonstration of ongoing training or instruction. As summarized in my C.V., I have been a member of RAPS throughout my consulting career. During my tenure as RAPS Vice President of Education, I participated in the establishment of the certification program and its qualifying criteria. In 2010 I was selected as a RAPS Fellow, a distinction awarded to senior regulatory professionals for their continued significant contributions and leadership in the advancement of the profession.

1.8. I serve as an elected member of the Society of Quality Assurance (SQA) Education Committee and I am an instructor for their quality college. SQA is an organization of professionals dedicated to the exchange and utilization of knowledge in research and regulatory quality assurance. I also serve on the board of the American Society of Quality (ASQ) – FDC Division. With more than 85,000 members, ASQ is a global community of experts and the leading authority on quality in all fields, organizations, and industries.

2. Other Expert Testimony

2.1. Exhibit 2 contains a list of expert testimony and depositions that I have provided during the last five years.

3. Bases for Opinion

3.1. Experience and Documents Reviewed

3.1.1. At the request of counsel, I reviewed deposition transcripts, exhibits and other documents involved in this case that are related to the FDA approval and manufacture of Digitek® (a brand of digoxin) tablets by Actavis. (These documents are listed in Exhibit 3.)

3.1.2. Counsel requested that I evaluate the information contained in these documents and consider the Actavis experience with Digitek® in view of my knowledge of and experience with other manufacturers of FDA approved finished pharmaceuticals.

3.1.3. In my review, evaluation, and consideration of the information presented in this case, I drew upon my knowledge and understanding of pharmaceutical industry practices as well as FDA regulations, guidelines, and enforcement policies obtained from 38 years of professional experience of FDA regulatory matters, as outlined in the first section of this statement. This includes practical training in industrial pharmacy as well as witnessing many drug manufacturing activities. My professional experience is enhanced by an extensive library of FDA regulatory material that is regularly updated. I subscribe to and regularly read numerous sources of information about FDA regulations, enforcement actions, policies, procedures, and guidelines.

3.2. Regulatory Background

3.2.1. Drug Product Approval Process

3.2.1.1. Digoxin (the generic name for Digitek®) has been used for centuries to treat various heart conditions; therefore, its use precedes the 1938 passage of the Federal Food Drug, and Cosmetic Act (FD&C Act). For many years digoxin was marketed without formal FDA review and approval but that changed in 1974 when FDA announced that digoxin drug products for oral use

are "new drugs" under the provisions of the FD&C Act and are required to be submitted to the FDA for formal review and approval before marketing.[1]

3.2.1.2. Between 1974 and 2002 FDA regulated oral digoxin products through 21 C.F.R. 310.500 that required a mandatory batch certification program in which FDA independently tested samples from every batch of oral digoxin products before distribution. In 2002 FDA revoked 21 C.F.R. 310.500 and required that manufacturers submit and gain approval of new drug applications (NDAs) or abbreviated new drug applications (ANDAs) to market oral digoxin drug products.

3.2.1.3. An NDA is a lengthy and detailed file which contains evidence and data to demonstrate that a drug product is safe and effective for its labeled use(s). An NDA contains data from pre-clinical (laboratory and animal) and clinical (human) safety and effectiveness studies as well as detailed information about the chemistry, manufacture and control of the active pharmaceutical ingredient and finished drug product[2]. Since Digitek® was the subject of an ANDA, not an NDA, I will focus on the content of an ANDA.

3.2.1.4. An ANDA is a type of NDA which also contains detailed information about the chemistry, manufacture, and controls over the drug product which it describes[3]. Information includes the location of manufacturing facilities and quality control laboratories which support manufacture, testing, and release of drug product to the market. Also, the ANDA contains documentation associated with at least one batch of drug product, i.e., a copy of the batch production record, analytical test data for raw materials, in-process drug product, and the finished drug product. Finally, the ANDA contains stability data, i.e., analytical test data for at least one batch of drug product which has been held in storage for several months and tested at designated time points to demonstrate that the drug product continues to meet its release specifications throughout its shelf-life.

3.2.1.5. An ANDA is a 'living' document in the sense that it is routinely updated or modified to describe current controls associated with the drug product it describes. During the pre-approval review period, FDA reviewers frequently

[1] 39 FR 2471, January 22, 1974
[2] 21 CFR 314 Subpart B.
[3] 21 CFR 314 Subpart C.

raise technical questions, or request specific changes, which are characterized as "deficiencies" and documented in "non-approval" letters. ANDA sponsors respond to the deficiencies in the form of amendments. All amendments are cleared (i.e., approved, not approved, withdrawn) before an ANDA is approved.

3.2.1.6. After a drug is approved, ANDA sponsors are required to update their applications with various post-approval submissions. Certain types of post-approval reports include changes which are considered significant enough to require either notification or prior approval before implementation. [4] These post-approval ANDA submissions are known as "supplements".

3.2.1.7. Both amendments and supplements must clearly describe the change(s) to conditions for marketing as well as data to support the technical, clinical, or regulatory validity of proposed modifications. Therefore, amendments and supplements frequently include copies of manufacturing records and analytical test data. Frequently, they also contain additional stability data.

3.2.1.8. Regardless of whether an ANDA sponsor has filed a supplement, FDA regulations require that an annual report be submitted for each application.[5] Each annual report must contain chemistry, manufacturing, and controls changes, including updated stability data and reports of experiences, investigations, studies, or tests involving chemical or physical properties, or any other properties of the ANDA drug.

3.2.1.9. When the following is received or known to the ANDA sponsor, a "Field Alert" report must be submitted[6]: (i) information concerning any incident that causes the drug product or its labeling to be mistaken for, or applied to, another article; (ii) information concerning any bacteriological contamination, or any significant chemical, physical, or other change or deterioration in the distributed drug product, or any failure of one or more distributed batches of the drug product to meet the specification established for it in the application.

3.2.1.10. As the foregoing paragraphs demonstrate, ANDA sponsors and FDA are in frequent communication before and after a drug product is marketed regarding manufacturing processes and laboratory controls, as well as actual production experience and drug product test results.

[4] 21 CFR Part 314.
[5] 21 CFR 314.81(b)(2).
[6] 21 CFR 314.81(b)(1)

3.2.2. Current Good Manufacturing Practices (CGMP)

3.2.2.1. In addition to the requirements for submission, approval, and maintenance of ANDAs, the FD&C Act and FDA regulations[7] require that drugs be manufactured according to CGMP. CGMP covers a variety of matters which, collectively, results in a high degree of assurance that drug products meet their specifications for identity, strength, quality, and purity throughout their shelf-life.

3.2.2.2. To comply with the CGMP regulations, drug product manufacturers must validate drug manufacturing processes and controls as well as adequately monitor and control their facilities and operations to ensure that every portion of every batch will consistently meet quality specifications and that every batch can be made in a reproducible manner.

3.2.2.3. To validate manufacturing processes and controls, drug product manufacturers must successfully complete a series of complex and multi-level activities that include the installation, operation, and performance qualification of manufacturing and testing equipment and the validation of manufacturing processes. Validation studies demonstrate that the manufacturing procedures and controls, as described in master production records (i.e., manufacturing instructions), are appropriate to ensure that batches of drug product uniformly and consistently meet pre-determined specifications.

3.2.2.4. Quality control of drug products is required by the CGMPs, but the regulations recognize that product failures sometimes occur and they allow products to be reprocessed to meet specifications.

> Drug products failing to meet established standards or specifications and any other relevant quality control criteria shall be rejected. Reprocessing may be performed. Prior to acceptance and use, reprocessed material must meet appropriate standards, specifications, and any other relevant criteria.[8]

Reprocessing typically involves repeating a manufacturing or packaging step in order to eliminate or correct a product-related defect.

[7] 21 CFR Parts 210 and 211
[8] 21 C.F.R. 211.165(f)

3.2.2.5. 21 C.F.R. 211.192 requires the investigation of discrepancies or batch failures. The scope, depth and conduct of investigations vary depending upon the circumstances which need further review and examination. Current industry practice, and FDA expectation, requires that companies diligently try to find the root cause for a discrepancy or failure; however, sometimes the root cause is elusive and investigations are closed without ever identifying the cause. Failure to identify the root cause of a discrepancy or failure is not a violation of CGMP.

3.2.2.6. It is noteworthy that, unlike some universal plumbing and electrical standards, CGMP is general in nature and lacks specificity in defining control requirements. Each drug product manufacturer must interpret the regulations and define and apply the specific controls it determines necessary to assure the quality of their drug products. For example, the regulation pertaining to manufacturing equipment design, size, and location states:

> Equipment used in the manufacture, processing, packing, or holding of a drug product shall be of appropriate design, adequate size, and suitably located to facilitate operations for its intended use and for its cleaning and maintenance.[9]

Clearly, this standard needs further definition before it can be applied in a manufacturing environment and, consequently, companies use their discretion to apply various ways and methods to achieve compliance.

3.2.3. CGMP Factory Inspections and Drug Product Surveillance

3.2.3.1. FDA conducts comprehensive regulatory coverage of all aspects of production and distribution of drug products to assure that such products meet CGMP requirements of the FD&C Act, using two basic strategies to realize this goal.

> Factory Inspections - To evaluate the conditions and practices under which drug products are manufactured, packed, tested and held.

[9] CFR 211.63

Drug Product Surveillance Analysis - To monitor the quality of drug products through surveillance activities such as sampling and analyzing drugs in distribution.[10]

3.2.3.1.1. Factory Inspections

3.2.3.1.1.1. FDA inspects drug product manufacturers by concentrating their attention on those "systems" which have the greatest impact on drug product quality. Examination of the following systems is meant to provide a broad and deep evaluation of a firm's CGMP compliance.[11]

- Quality System
- Facilities and Equipment System
- Materials System
- Production System
- Packaging and Labeling System
- Laboratory Control System

3.2.3.1.1.2. During their inspection of drug product manufacturers, FDA investigators assess company compliance with CGMPs based on their interpretation of the regulations from related experience and training. It is common for FDA investigators to find and report CGMP deficiencies which they record on Form FDA 483, a copy of which is issued to and discussed with facility management at the close of an inspection. During fiscal year 2008, FDA issued 4,987 Forms FDA 483 during 15,245 inspections.[12]

3.2.3.1.1.3. The observations recorded on the Form FDA 483 are not necessarily violations of FDA law or regulations. In fact the form states this fact before any observations are presented:

> This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance.[13]

[10] Compliance Program Guidance Manual # 7356.002, Drug Manufacturing Inspections
[11] Ibid.
[12] www.fda.gov/downloads/ICECI/EnforcementActions/EnforcementStory/UCM129824.pdf
[13] Form FDA 483; Investigations Operations Manual Section 5.2.3.1.4

3.2.3.1.1.4. FDA's Investigations Operations Manual, Section 5.2.3.3, cautions investigators about Form FDA 483:

> Do not report opinions, conclusions, or characterize conditions as "violative." The determination of whether any condition is violative is an agency decision made after considering all circumstances, facts and evidence.

3.2.3.1.1.5. Section 5.2.7 of FDA's Investigations Operations Manual further advises investigators about discussion of Form FDA 483 observations with management.

> During the discussion be frank, courteous and responsive with management. Point out the observations listed on the FDA 483, are your observations of objectionable conditions found during the inspection, and explain the significance of each… You should inform management during the closeout discussion the conditions listed may, after further review by the Agency, be considered to be violations of the Food, Drug and Cosmetic Act or other statutes. .. Explain, in your judgment the conditions you observed MAY be determined by the FDA, after review of all the facts, to be violations.

3.2.3.1.1.6. The Form FDA 483 ultimately becomes part of the Establishment Inspection Report (EIR), written by the investigator(s) to more fully describe the inspection, persons interviewed and results of meetings with management, documents examined, and operations observed.

3.2.3.1.1.7. Another aspect of FDA inspections can be the collection of physical samples at factory sites. Instructions to investigators state:

> Samples of defective product constitute persuasive evidence that significant CGMP problems exist. Physical samples may be an integral part of a CGMP inspection where control deficiencies are observed.

Investigators may decide independently or in consultation with their supervisor whether to collect such evidentiary samples.

Physical samples are usually not collected unless the investigator believes they include defective product.

3.2.3.1.1.8. The EIR, Form FDA 483, and physical sample test results, when available, are reviewed by a district level supervisory investigator who classifies the inspection according to one of three compliance categories: NAI (No Action Indicated), OAI (Official Action Indicated), or VAI (Voluntary Action Indicated).[14]

- An NAI classification means that the facility was found to be in substantial compliance with the regulations.
- An OAI classification means that regulatory action (e.g., Warning Letter, seizure, injunction, or prosecution) will be recommended.
- A VAI classification means that objectionable conditions were found but that FDA is not prepared to take regulatory action since the objectionable conditions do not meet the threshold for regulatory action. Any corrective action is left to the establishment to take voluntarily.

3.2.3.1.1.9. EIRs, classified as VAI or OAI, are referred to a district-level compliance officer for further review and evaluation. Sometimes EIRs are also referred to compliance officers in FDA headquarters (e.g., Center for Drug Evaluation and Research) for even further review and evaluation. Finally, recommendations for regulatory actions such as Warning Letters, seizure, injunction, or prosecution involve additional FDA levels of review and concurrence.

3.2.3.1.2. Drug Product Surveillance

3.2.3.1.2.1. In addition to conducting factory inspections, FDA surveys drugs marketed within the United States as another method to monitor the CGMP compliance of drug product manufacturers. The drug product surveillance program assumes that information derived

[14] http://www.fda.gov/ICECI/Inspections/FieldManagementDirectives/ucm061430.htm

> from direct product analysis is important in itself, apart from information obtained about the process that produced the product.[15]

3.2.3.1.2.2. One of the stated objectives of the drug product surveillance program is to obtain information about the quality of the nation's drug supply by product analysis of selected finished dosage forms. Periodic surveillance is designed to identify emerging problems with particular drug products.

3.2.4. FDA Regulatory Actions

3.2.4.1. The lack of an objective CGMP regulatory standard creates a challenge for the pharmaceutical industry and the FDA, causing inconsistent interpretation, inspection results, and enforcement actions. Drug product manufacturers vary considerably in their application of the CGMP regulations, resulting in a varied array of industry practices. Therefore, it is not uncommon for drug product manufacturers to be found in compliance during an inspection one year and out of compliance in the following year. Nor is it uncommon for a drug factory to be found out of compliance during an inspection in one district while another district accepts similar practices in another drug factory.

3.2.4.2. Nonetheless, when FDA believes that companies have violated the FD&C Act, it can rely on a variety of enforcement tools. The Warning Letter is typically the first level of regulatory action. It is intended to achieve voluntary compliance and provide notification to company management of FDA concerns when a violative situation does not present a danger to health or does not constitute intentional, gross or flagrant violations.[16] During fiscal years 2007 and 2008, FDA issued 471 and 445 Warning Letters respectively.[17]

3.2.4.3. FDA regulatory actions (e.g., Warning Letter, seizure, injunction, or prosecution) based on CGMP deficiencies do not require evidence that defective or unsafe product be identified. In fact, FDA instructs its compliance officers,

> It is not mandatory to demonstrate that the law has been violated to seek an injunction, only that there is likelihood that it may be violated if an injunction is not entered.[18]

[15] FDA Compliance Program Guidance Manual # 7356.008 Drug Product Surveillance
[16] FDA Regulatory Procedures Manual, Sections 4 and 10.
[17] www.fda.gov/downloads/ICECI/EnforcementActions/EnforcementStory/UCM129824.pdf
[18] FDA Regulatory Procedures Manual, Section 6

3.2.4.4. Regulatory Actions – Adulterated Products

3.2.4.4.1. According to 21 U.S.C. § 351(a)(2)(B), a drug shall be deemed to be adulterated:

> If it is a drug and the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirements of this Act as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess.

3.2.4.4.2. This legal definition of "adulterated" does not mean that a drug is unsafe or otherwise defective or unfit for use. Nor does it mean that out-of-specification drug products have been distributed. FDA regulatory actions against companies with poor CGMPs are taken as a preventive measure. When issuing press releases about such regulatory actions and even related drug recalls, FDA typically advises consumers who are taking drugs from a company that was not following CGMPs not to interrupt their drug therapy, which could have serious implications for their health[19].

3.2.4.5. Regulatory Actions - Application Integrity Policy

3.2.4.5.1. As a consequence of wrongdoing on the part of some pharmaceutical companies and FDA employees in the late 1980's and early 1990's, FDA developed and implemented the Application Integrity Policy to ensure validity of data submissions, to withdraw approval of, or refuse to approve, applications containing fraudulent data. [20]

3.2.4.5.2. According to this program, FDA may "debar" individuals and companies if they are convicted of certain felonies or misdemeanors, such as those related to the drug approval process or FDA's regulation of drugs

[19] http://www.fda.gov/Drugs/DevelopmentApprovalProcess/Manufacturing/ucm169105.htm
[20] FDA Compliance Policy Guide Sec. 120.100 Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities

in general. Once individuals have been debarred, they may no longer work for anyone with an approved or pending drug product application at FDA. A debarred company cannot submit, or assist others in submitting, ANDAs.

3.2.4.5.3. Since the policy was implemented, FDA's inspections have placed more emphasis on data integrity to ensure that data upon which drug approval is based are accurate and complete.[21] During their inspections, FDA investigators audit raw data to authenticate information submitted in drug approval applications (NDAs and ANDAs) and to verify that all relevant data were submitted. Typical documentation reviewed during such an audit includes batch production records, raw material records, and laboratory testing records.

3.2.4.5.4. Violations of the Application Integrity Policy can result in product approval delays, denial of product approval, withdrawal of product approval, and debarment of individuals and companies.

3.2.4.6. Drug Product Recalls

3.2.4.6.1. Drug product recalls are not FDA regulatory actions and FDA does not have the authority to recall drug products. Nonetheless, companies may voluntarily recall products when FDA has expressed concern about product quality from CGMP focused inspections. Recalls are not uncommon events. During fiscal years 2007 and 2008, more than 10,000 products were recalled (5,585 and 5,778 products respectively).[22]

3.2.4.6.2. A product recall is a voluntary action taken by manufacturers and distributors to protect the public health from products that present a risk of harm or injury or are otherwise defective.[23] There need not be objective evidence that defective, harmful or out-of-specification product is on the market for a recall to occur.

3.3. Factual Background

[21] FDA Compliance Program Guide 7346.832
[22] Ibid.
[23] 21 Code of Federal Regulations 7.40 Recall Policy

3.3.1. In accordance with 21 C.F.R. 314.500, Amide participated in the digoxin batch certification program which required that samples from each batch of Digitek® be tested and cleared by FDA. The regulations also required that Amide submit their laboratory test results for each batch of Digitek®. On July 20, 1995, after numerous batches passed testing and were certified for distribution, FDA exempted Amide from the batch certification program.[24]

3.3.2. After FDA began accepting applications for generic oral digoxin drug products in 1997, Amide Pharmaceutical, Inc. (later Actavis) submitted an ANDA for Digitek®, receiving approval on December 23, 1999. As described earlier in this report, the ANDA contained detailed information about the chemistry, manufacture, and control of Digitek®, including data from batch production records and laboratory testing of in-process, finished product, and stability samples.

3.3.3. In January 2002 Amide filed a prior approval supplement to its Digitek® ANDA, along with supporting documentation and data, requesting a change in the product manufacturing instruction to adjust the quantity of digoxin added to each batch based on the assay results of the active ingredient. FDA approved the supplement in June 2002. [25]

3.3.4. After Digitek® approval, Amide and later Actavis filed annual reports according to the requirements of 21 C.F.R. 314.81. During the years 2003 through 2007 the company reported on the experience of manufacturing 209 batches (more than one billion tablets) of Digitek® 0.125 mg drug product and 219 batches of Digitek® 0.25 mg drug product (more than 900 million tablets). During that time, all released batches were found to be within specifications.[26] Also, all sample test results from thirty-six month stability studies were found to be within specifications. [27]

3.3.5. In accordance with 21 C.F.R. 211.180 (General Requirements), Actavis performed annual product reviews with the same results as described above.[28]

3.3.6. In accordance with CGMP requirements, Amide successfully completed process validation studies as summarized below. These validated processes were used to manufacture the products until they were discontinued in 2008. Revalidation is not required unless significant process changes occur.

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[24] Document number 0009.
[25] ACTAV 000006497-8
[26] An out-of-specification investigation for blend uniformity was conducted on one lot, batch # 60992A, 0.125 mg; however, the investigation and additional testing invalidated the initial result and the batch was released for distribution.
[27] ACTAV 000005687-6026, 6042-6145, 6201-6436, 6484-6488, 6489-6508
[28] ACTAV 000005658-5686, 6027-6041, 6146-6260, 6437-6483, 6509-6541

- Digitek® 0.125 mg, 1,600,000 tablet batch size, validated in December 1994 and March 1995[29].
- Digitek® 0.125 mg, 4,800,000 tablet batch size, validated in September, 1996.
- Digitek® 0.25 mg, 4,200,000 tablet batch size, validated in January 1995.
- Digitek® 0.5 mg, 4,200,000 tablet batch size, validated in November 1994.

3.3.7. The equipment used to manufacture Digitek® (i.e., twin shell blender, double cone blender, BB Stokes tablet press) has been and continues to be used in the pharmaceutical industry. According to the documents I reviewed, FDA never criticized the make, model, or age of the manufacturing equipment

3.3.8. In accordance with 21 C.F.R. 211.22, Actavis had a quality control unit with the responsibility and authority to approve or reject all components, drug product containers, closures, in-process materials, packaging material, labeling, and drug products, and the authority to review production records to assure that no errors have occurred or, if errors have occurred, that they have been fully investigated.

3.3.9. From 2005 until Digitek® production was halted, no incidents occurred which required Amide (later Actavis) to submit a field alert to FDA notifying them of a problem with a distributed drug product.

3.3.10. FDA inspected Actavis in September 2007, covering all systems (Quality, Production, Laboratory Control, Materials, Facilities, and Equipment), classifying the inspection as "VAI" [30] (Voluntary Action Indicated).

3.3.11. The quality unit of Actavis complied with 21 C.F.R. 211.192 (Production Record Review) in its release of Digitek® lot 70924A. During the packaging of this lot, two tablets with approximately double the normal thickness were found from packaging machine counter channels. Packaging operators then performed a 100% inspection on the tablets from the hopper (tablet bucket numbers 15 & 16) as well as the two subsequent buckets (17 & 18). One more tablet was identified in bucket number 17. Packaging continued while the operators performed a continuous inspection of the tablets. While inspecting the final bucket (number 34), two more tablets were identified, bringing the total of double thick tablets to five. The batch record for previous manufacturing steps was reviewed and evaluated. Then, every tablet in the

[29] This validation included tablet press speeds up to 28 rpm.
[30] As described earlier in this report, VAI is an inspection classification meaning that objectionable conditions do not meet the threshold for regulatory action.

batch was visually inspected, resulting in the identification of fifteen more double-thick tablets, bringing the total to twenty. As a final control to ensure that all affected tablets had been identified, rejected, and removed from the batch yet another visual inspection (a tightened AQL (acceptance quality level)) was performed. These actions were consistent with the language in 21 C.F.R. 211.192 which allows an investigation to be limited to one batch and one product.

> All drug product production and control records, including those for packaging and labeling, shall be reviewed and approved by the quality control unit to determine compliance with all established, approved written procedures before a batch is released or distributed. Any unexplained discrepancy (including a percentage of theoretical yield exceeding the maximum or minimum percentages established in master production and control records) or the failure of a batch or any of its components to meet any of its specifications shall be thoroughly investigated, whether or not the batch has already been distributed. The investigation shall extend to other batches of the same drug product and other drug products that may have been associated with the specific failure or discrepancy. A written record of the investigation shall be made and shall include the conclusions and follow-up.

3.3.12. Lot 70924A was reprocessed through repeated inspections to ensure that it met appropriate standards and specifications as allowed by 21 C.F.R. 165(f).

3.3.13. Visual inspection is an accepted quality control method. According to Juran's Quality Handbook, "Visual inspection remains the largest single form of inspection activity."[31]

3.3.14. FDA did not collect any physical samples of drug products in support of their findings during the 2008 inspection. According to FDA internal instructions, it appears that the FDA investigator did not believe that samples would provide persuasive evidence that significant CGMP problems existed.

3.3.15. The FDA investigator demonstrated a lack of understanding of quality systems in her inconsistent analysis of inspectional observations when she reportedly advised Actavis management that "one of the best outcomes of the Inspection was the input from the laboratory" followed by the statement, "… from a Quality Systems standpoint, there was "Total Failure".[32] It is not possible to have a totally failing quality system when the laboratory is found to be acceptable.

[31] Juran, Joseph, Juran's Quality Handbook, Fifth Edition, McGraw-Hill, Section 23.26
[32] Memo of Inspection Closeout, May 20, 2008. ACTAV 000543001-4.

3.3.16. In accordance with FDA's drug surveillance program, Digitek® samples from marketed batches were randomly selected and tested by FDA over several years. All samples were found to be within specifications as summarized below.

Lot # Product	**FDA Sample # Sample size**	**Date Collected Location**	**Date of Results**	**Results/Conclusions**
70298A1 0.125 mg	448881 2 x 100 ct bottles	12/3/2007 WalMart Pharmacy Warehouse, Crawfordsville, IN	4/30/2008	In Compliance – meets specifications for identification, dissolution, content uniformity.
70664A1 0.25 mg	448892 2 x 100 ct bottles	12/3/2007 WalMart Pharmacy Warehouse, Crawfordsville, IN	4/29/2008	In Compliance – meets specifications for identification, dissolution, content uniformity.
70811A1 0.25 mg	454866 2 x 100 ct bottles	2/15/2008 McKesson Drug Co., Duluth, GA	6/5/2008	In Compliance – meets USP specifications for identification, dissolution, content uniformity.
8A332 0.25 mg	462753 2 x 180 ct boxes	3/21/2008 WalMart, Hanford, CA	9/23/2008	In Compliance – meets specifications for identification, dissolution, content uniformity.
70078A1 0.125 mg	377410 2 x 180 ct boxes	2/9/2007 Actavis (Taft Rd)	7/5/2007	Meets specifications for assay, content uniformity, dissolution, organic volatile impurities.
70737A1 Strength unknown	453913 1 x 1000 ct box	2/15/2008 Dealer name purged	6/10/2008	In Compliance – meets USP specifications for identification, dissolution, content uniformity.
Unknown 0.125 mg	157503 Unknown	Unknown	7/12/2002 11/1/2002	In Compliance – meets USP specifications for uniformity of dosage units and dissolution.
Unknown 0.125 mg	178891 Unknown	Unknown	4/2/2003	No action indicated. (NAI)
Unknown 0.125 mg	157504 Unknown	Unknown	7/12/2002 11/1/2002	In Compliance – meets USP specifications for uniformity of dosage units and dissolution.

Lot # Product	FDA Sample # Sample size	Date Collected Location	Date of Results	Results/Conclusions
Unknown 0.125 mg	178890 Unknown	Unknown	4/2/2003	In Compliance.

3.3.17. In addition to FDA's laboratories, other independent laboratories (Celsis on behalf of Mylan) tested Digitek® samples and found them to be within specifications.[33] Also, Quantic Regulatory Services, LLC, performed a third party audit of recalled Digitek® batches which revealed no evidence that defective drug product had been distributed.

3.3.18. During the 2008 FDA inspection, Actavis management decided to voluntarily recall all strengths and lots of Digitek®. The company's April 25, 2008 press release, which was approved by FDA[34], stated: "The voluntary all lot recall is due to the possibility that tablets with double the appropriate thickness may have been commercially released."[35] The recall did not mention dose variability (i.e., the presence of more or less active drug ingredient in different tablets) in normal sized tablets.

3.3.19. Actavis reported that it had chosen to voluntarily recall products as a good faith measure to move forward and remove any doubt in the mind of the Agency regarding product quality.[36]

3.3.20. FDA notified the public about the Digitek® recall by posting the following information on its website. FDA did not advise patients to stop taking the drug.

> The product is being recalled due to the possibility that tablets with double the appropriate thickness may contain twice the approved level of active ingredient… Patients should contact their healthcare professional with questions.

3.3.21. A year after the recall, in the publication "Facts and Myths about Generic Drugs", FDA stated the following about the Digitek® recall.

[33] UDLL 000011679-11769, Digitek® list of recalled batches; Defendants exhibits 83 and 84.
[34] Deposition of Misbash Sherwani, page 158.
[35] http://ww.fda.gov/SafetY/Recalls/ArchiveRecalls/2008/ucm112435.htm
[36] ACTAV 00918572 (Actavis Corrective Action Plan Status Report, 8/28/08, Lambridis Deposition Exhibit 108 page 6)

In our best judgment, given the very small number of defective tablets that may have reached the market and the lack of reported adverse events before the recall, harm to patients was very unlikely.

3.3.22. FDA never raised concerns about the integrity of individuals developing data to support and maintain the Digitek® ANDA approval or proposed any debarment actions or enforce the application integrity policy.

4. Opinion

4.1. The Digitek® manufacturing process had been validated, thereby demonstrating a reliable and consistent process. I did not observe documentation that FDA ever found the Digitek® process validation, or underlying manufacturing equipment qualification, studies to be insufficient or invalid. Therefore, I have no reason to believe that the validation was inadequate.

4.2. The type of blenders (twin shell, double cone) and tablet compression equipment (Stokes BB2) used to manufacture Digitek® is well known in the industry and has been used throughout the world for many years. I did not observe documentation that FDA found the equipment inappropriate or unfit for use.

4.3. The investigation of double-thick tablets in Digitek® lot 70924A and subsequent inspection were based on sound quality principles. The Digitek® distributor, Mylan Pharmaceutical, accepted the scope and conduct of the investigation and visual inspection, and the ultimate release of the drug product to them for distribution. The positive nature of Digitek® manufacturing and distribution history over many years, documented in annual product reviews and ANDA annual reports, supported a quality conclusion that the incident associated with lot 70924A was isolated and could be managed with multiple visual inspections.

4.4. Not long before double-thick tablets were observed in Digitek® lot 70924A, FDA had conducted a comprehensive inspection which failed to identify any objectionable conditions serious enough for regulatory action thereby giving confidence to company management that their quality system, including deviation management, was compliant.

4.5. During the close-out of the 2008 inspection, the FDA investigator contradicted herself by stating that the quality system was a total failure at the same time she stated that “one of the best outcomes of the inspection was the input from the laboratory”. Such an inconsistent opinion undermines the credibility of the investigator. The laboratory is an

integral part of the quality unit and, therefore, part of the quality system. Also, she failed to comply with FDA instructions prohibiting the issuance of opinions or conclusions about violations. Finally, FDA investigators do not have the authority to make the final determination about CGMP compliance; therefore, her stated opinion is not the opinion of the agency.

4.6. FDA accepted Digitek® ANDA, manufacturing, and quality control documentation and data according to FDA's Application Integrity Policy, thereby providing assurance that recorded batch histories and laboratory data were trustworthy.

4.7. FDA and third party laboratories provided numerous independent results which demonstrated that distributed batches of Digitek® met all specifications, another indication that the Actavis laboratory results were valid and that the quality system was not totally failing. During the 2008 inspection, the FDA investigator did not collect any physical samples, presumably because she did not believe they would demonstrate that significant CGMP problems existed.

4.8. According to FDA documents[37], the reason for the recall of Digitek® batches was limited to the possibility that tablets with double the appropriate thickness may have been commercially released and did not extend to tablet variability from other potential causes. FDA did not claim that double-thick tablets had been released and distributed.

4.9. Although I reviewed numerous documents related to the company's CGMP compliance history, and am aware of the Form FDA 483s and Warning Letters issued from 2006 to 2008, I observed no documentation to demonstrate that any of the recalled Digitek® batches contained double-thick or otherwise out-of-specification drug product or that any consumer ever received a double-thick tablet.

Martha M. Bennett

Martha M. Bennett, RAC

Dec 13, 2010

Date

[37] http://www.fda.gov/Safety/Recalls/ArchiveRecalls/2008/ucm112435.htm, http://www.fda.gov/Safety/Recalls/EnforcementReports/2008/ucm120518.htm

EXHIBIT 1

Bennett and Company

Martha M. Bennett, RAC
President

EXPERIENCE

1985-Present **Independent Consultant, FDA related matters**

Quality Systems & Risk Management
(Current Good Manufacturing and Laboratory Practices, ICH, ISO, HACCP)
- conduct site audits
- conduct in-plant training
- write/review SOPs
- write/review GMP (CMC) sections of FDA submissions
- respond to FDA inspections (FD-483s); consent decree support
- process and computer validations
- risk-based quality management systems

Clinical Investigations, Institutional Review Boards
- conduct site visits
- audit clinical investigators
- overall review of INDs and IDEs

510(k)s, PMAs, NDAs, ANDAs, IDEs, INDs, PLAs, ELAs
- conduct comprehensive audits of submissions
- develop overall strategy
- write/review technical sections
- facilitate communications with FDA

Product Complaint Systems
- conduct independent investigations
- develop complaint handling systems and procedures

Other
- U.S. Agent duties
- review product labels for compliance with FD&C Act and regulations, including OTC monographs
- testify in FDA related litigation
- FDA regulatory research

1982-1985 **Supervisory Policy Analyst, FDA Office of Commissioner**

- write responses to incoming correspondence
- prepare Commissioner for meetings, Congressional hearings
- manage staff of policy analysts
- analyze policy decisions, recommend actions
- prepare briefing books for meetings, Congressional testimony
- assist in overall management of Commissioner's duties

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Bennett and Company

1977-1982 **Senior Compliance Officer, FDA Bureau of Drugs**

- recommend approval/disapproval of regulatory actions
- manage litigation, prepare expert witnesses, testify
- participate in agency-wide policy development committees
- write GMP regulations
- manage FDA Emergency Command Center
- develop in-depth investigations related to NDA violations
- manage administrative hearings on new drug matters

1972-1977 **Investigator, Nashville District Office**

- conduct full range of inspections and investigations
- conduct lengthy undercover investigation of health fraud
- District recall coordinator
- testify in FDA litigation

EDUCATION

1972-Present I have followed a continuing education program of self-study as well as short-term and graduate courses to enhance my work. Subjects include: validation, ISO standards, software development, food science, food and drug law, pharmacology, computer science, business management, microbiology, and industrial pharmacy.

I attend and participate in professional meetings where new policies and procedures are presented. I subscribe to numerous professional and technical journals in order to remain up-to-date on FDA matters.

Regulatory Affairs Certified

1972 B.S. Zoology, Chemistry - University of Tennessee

AWARDS and RECOGNITION

2010	Excellence in Humanity Award (Rotary)
	Who's Who (United)
	Who's Who of American Women
2004, 2002	Rotarian of Year
1974, 1976, 1984, 1985	FDA Awards – Commendable Service Award, Cash Award, Commendation, Commissioner's Citation

ASSOCIATIONS (Current)

Food and Drug Law Institute (FDLI)
American Society of Quality Control, Society of Quality Assurance (ASQC; SQA)
Chairman VOC Committee; Education Committee

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Regulatory Affairs Professionals Society (RAPS)
- 1986 Annual meeting program committee
- 1987 Chairman, Annual meeting program committee
- 1988 Chairman, Annual meeting program committee
- 1989 Vice President, Programs

Parenteral Drug Association (PDA)
International Society for Pharmaceutical Engineers (ISPE)

PAPERS AND PRESENTATIONS

2000 - Present	Instructor, Center for Professional Advancement - Medical Device QSR
2010	SQA Quality College – Lab to Market – Product Approvals
1988-1994	Co-Director, Center for Professional Advancement – GMPs (Drugs, Devices)
2008-2009	FDA Infant Formula regulations; GMPs; validation (Nestlé, E.U.)
2007	Medical Device QSR – Philips (Medical)
2006	Deviation Control, Genetic Engineering, May 15, 2006; WebCast August 2006
	Quality systems in bioanlaysis (MDS Pharma)
2005	Risk-based quality management systems (MDS Pharma)
	Events resolution and investigation (MDS Pharma)
	Pharmaceutical cGMPS (MDS Pharma)
	Quality systems in bioanalysis (MDS Pharma)
2004	Customer Complaint Handling (Telerx)
	Pharmaceutical cGMPS (Fort Dodge Animal Health)
	Quality Auditing, Corrective Actions (Continuing Education Conference)
2003	Equipment Qualification and Process Validation (Perfectseal)
	Customer Complaint Handling (Roho Group)
2002	Change Control Requirements (Client)
2001	Current Good Manufacturing Practices (Client)
	Validation & Part 11(Client)
	Technical and Development Reports (Society of Quality Assurance)
2000	How to Conduct Internal Investigations
	Documentation of Internal Investigations
1999	Document Control in Laboratories
	General Laboratory Controls (Watson Pharmaceutical)
	CGMPs for Laboratories (Watson Pharmaceutical)
	How to Conduct Failure Investigations (Watson Pharmaceutical)
	CGMP update (Watson Pharmaceutical)
1998	GMPs in R&D Laboratories
	Infant Formula GMPs (Nestlé)
	Technical Writing for FDA Submissions
1997	Pre-Approval Inspections – IPS
	Infant Formula GMPs (Nestlé)
1996	Technology Transfer - FDA Regulatory Considerations; ISPE
	IPS - Pre-Approval Inspection Program
1995	GMP Training Manual
	Drug and Device GMPs, Edison Biotech Center
	The Cost of Compliance, HIMA In-Vitro Diagnostic Conference
1994	A Practical Guide to Validation Documentation

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	Pre-Approval Inspections, ISPE Spring Meeting
	Medical Device GMPs, Edison Biotech Center
	ANDA Compliance Issues, NAPM Fall Meeting
1993	Pre-Approval Inspections, ISPE Spring Meeting
1992	Speech on GMPs, Annual Meeting, Society for Quality Assurance
1991	Speech on Responding to FD-483s, NAPM
1990	Speech on Lessons from Generic Drug Scandal, NPA
	Lecturer, Chromatography & Biotechnology Conference
1989	Lecturer, Good Clinical Practices, Interpharm
	RAPS workshop director and speaker GMPs and Chromatography – Washington Chromatography Discussion Group
1988	Guest Lecturer, Florida Atlantic University
1987	Regulatory Compliance - GMPs
	Guest Lecturer, Florida Atlantic University
	GMPs and Separation Science, Varex Corporation
	"Prepare for FDA Inspection", Medical Device and Diagnostic Industry
1986	Bits and Bytes in Regulatory Affairs, RAPS annual meeting
1985	Management of Information, FDA Action Plan I
1984	FDA Update speech for Commissioner Hayes, Pharmacy Times

OTHER

Healthcare

1999-2010	Board of Trustees, Havasu Regional Medical Center - Chairman (2008-2010); Vice Chairman (2007-2008) - Hospital Volunteer – Auxiliary (2001 – 2010) - Quality Improvement Council (2003 - 2010) - Physician Recruitment Committee (2005-2009); - CEO, CNO Selection Committees (2004, 2006, 2007, 2008, 2009) - Medical and Board By-laws Committees (2004, 2006, 2007)
2002-2010	Board of Directors, Mohave Mental Health Clinic, Inc. - Chairman (2006- 2008), Vice Chairman (2004 – 2006) - Quality Improvement Steering Committee (2003 - 2010)
2008-2010	Board of Directors, Hospice of Havasu - Quality Assurance Program Initiative Committee - Board Development Committee - Fund-raising Committee - Major Donor - President (2010)
2006-2010	Lake Havasu City Waste Water Expansion Program Oversight Committee – largest sewer construction project in North America ($450M)
2007	Delegate – Arizona Governor's Strategy Session on Health Care

Humanitarian

2001-2010	Lake Havasu City Rotary Club - Excellence in Humanity Award - Multiple Paul Harris Fellow; Paul Harris Society - Vocational Program Committee (2002)

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- Paul Harris Foundation Coordinator (2003-Present)
- District Literacy Coordinator (2003)
- Rotary Youth Leadership Award (RYLA) Counselor (2004)
- Rotary International Major Benefactor (2004-2010)
- Rotary Foundation Bequest Society (2005-2010)
- Wheelchair Donations to Indigent in Mexico (2007)
- Various local partnerships to improve family and child lives.

Community

2000-2008	Partnership for Economic Development - Chairman of Board (2005 – 2007); Vice Chair (2004-2005) - Major Donor, Committee for Business Park Development (2004-2009) - Board of Directors (2002-2008) - Marketing Committee Chair (2000-2004) - Policies & Procedures Committee Chair (2003)
2001-Present	Chamber of Commerce - Various volunteer duties, as needed. - Donor golf tournament fundraisers
2006	President, Havasu 100. Delegate, Town Hall of Arizona – Public Health Needs
1997-2006	Instructor, Lake Havasu Literacy Council
2006-2007	Reading Coach, Smoketree Elementary School
2006-2008	R/UDAT Steering Committee Co-Chair; Connecting Havasu
1999-2000	Town Hall of Lake Havasu City – Board of Directors (2000); delegate (1999)
1996-2000	Western Arizona Humane Society - Vice President (2000) - Managing Director (1998 – 2000) - Board of Directors (1997 – 2000) - Volunteer (1996 – 2000) - Major Donor (196-2000)
1996-2010	Major donor or sponsor – Kiwanis Circus, LHC Film Festival, LHC Concert Series, Big Brothers Big Sisters, March of Dimes

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EXHIBIT 2

Testimony and Depositions, 2005 to Present

2005	Deposition	American Home Assurance vs. Merck about insurance claims associated with damaged drugs.
2008	Deposition	KDur antitrust litigation about FDA drug approval process, including cGMPs.
2008	Deposition Trial	Arava antitrust litigation about FDA drug approval process, including cGMPs.
2008	Deposition	Nifedipine antitrust litigation about FDA drug approval process, including cGMPs.

EXHIBIT 3

CD: 2nd FOIA Response Digitek Litigation		
Title	**Bates #**	**Description**
1995 Documents	008-009	FDA letters (1995, 1996) re batch certification.
Letter		Tucker, Ellis, West FOI request.
Mylan Documents	MYLN 00932682-3	Mylan email re Digitek recall.
Untitled 001		FDA sample documentation (462753)
Untitled 002		FDA sample documentation (462753)
Untitled 003		FDA sample documentation (377410)
Untitled 004		FDA sample documentation (453913)
Untitled 005		FDA sample documentation (453913)

CD: Golkow Technologies, Inc. In Re: Digitek Phyllis A. Lambridis January 18, 2010			
Title	**Bates #**	**No. of Pages**	**Description**
		399	Lambridis deposition transcript.

CD: EIR for 2008 inspection 5/20/08 Little Falls Inspection		
Title	**Bates #**	**Description**
5 20 08 Little Falls Inspection	ACTAV 000543001-4	May 2008 summary of inspection close-out meeting
Plaintiffs Deposition Exhibit 91		EIR from 2008 inspection.

CD: 70924A Batch Record		
Title	**Bates #**	**Description**
70924A Batch Record	000002653-000003149	Batch record for 70924A

CD: In Re: Digitek Batch records 70836 and 70925		
Title	**Bates #**	**Description**
Batch 70836		Batch record for 70836.
Batch 70925		Batch record for 70925.

CD: In Re: Digitek Expert Documents 04/08/10		
Title	**Bates #**	**Description**
Batch 60371	ACTAV 000003992-5	7104.pdf Batch records
	ACTAV 000003996-4012	7105.pdf Batch records
	ACTAV 000004013-8	7106.pdf Batch records
	ACTAV 000004104-4117	14825.pdf Batch records
	ACTAV 000648832-3	263368.tif Batch records
Batch 70025	ACTAV 000031027-9	8316.tif Batch records
	ACTAV 000031030-5	8317.tif Batch records
	ACTAV 000031037-53	8319.tif Batch records
	ACTAV 000031054-9	8320.tif Batch records
	ACTAV 000031170-80	14413.tif Batch records
Batch 70454	ACTAV 000044082-8	10393.tif Batch records
	ACTAV 000044089-94	10394.tif Batch records
	ACTAV 000044095-111	10395.tif Batch records
	ACTAV 000044115-120	10397.tif Batch records
	ACTAV 000044224-34	15483.tif Batch records
Batch 70559	ACTAV 000046613-21	8822.tif Batch records
	ACTAV 000046622-38	8823.tif Batch records
	ACTAV 000046648-53	8825.tif Batch records
	ACTAV 000046696-703	14597.tif Batch records
	ACTAV 00004779-90	15224.tif Batch records
Batch 70836	ACTAV 000056781-8	10932.tif batch records
	ACTAV 000056789-805	10933.tif Batch records
	ACTAV 000056891-6	10941.tif Batch records
	ACTAV 000056945-56	15612.tif Batch records
Batch 80002	11450	11450.tif Batch records
	11451	11451.tif Batch records
	ACTAV 001897687	11461.tif Batch records
	ACTAV 001897688	11462.tif Batch records
	ACTAV 001885282-97	16140.tif Batch records
Batch 80202	ACTAV 001884793-805	16060.tif Batch records
	ACTAV 001900180-96	77000.tif Batch records
	77001	77001.tif Batch records
	77002	77002.tif Batch records
	ACTAV 001900232	77011.tif Batch records
Batch 70207	ACTAV 000053977-84	9037.tif Batch records
	ACTAV 000053985-4001	9038.tif Batch records
	ACTAV 000054002-24	9039.tif Batch records
	ACTAV 000054025-9	9040.tif Batch records
	ACTAV 000054030-4	9041.tif Batch records
	ACTAV 000054035-48	9042.tif Batch records

	ACTAV 000054049-4100	9043.tif Batch records
	ACTAV 000054101-6	9044.tif Batch records
	ACTAV 000054107-15	9045.tif Batch records
	ACTAV 000054116-7	9046.tif Batch records
	ACTAV 000054118-37	9047.tif Batch records
	ACTAV 000054142	9050.tif Batch records
	ACTAV 000054143-50	14669.tif Batch records
	ACTAV 000054151-63	14670.tif Batch records
	ACTAV 000054164-76	14671.tif Batch records
	ACTAV 000054177-81	14672.tif Batch records
	ACTAV 000054182-5	14673.tif Batch records
	ACTAV 000054186-219	14674.tif Batch records
	ACTAV 000054220-7	15295.tif Batch records
	ACTAV 000054228-40	15296.tif Batch records
	ACTAV 000054241-53	15297.tif Batch records
	ACTAV 000054254-8	15298.tif Batch records
	ACTAV 000054259-62	15299.tif Batch records
	ACTAV 000054263-96	15300.tif Batch records
	ACTAV 000054297-304	19448.tif Batch records
	ACTAV 000054305-43	22169.tif Batch records
	ACTAV 000054344-57	22361.tif Batch records
	ACTAV 000054358-85	22362.tif Batch records
	ACTAV 000054386-431	22363.tif Batch records
	ACTAV 000054332-77	22364.tif Batch records
	ACTAV 000054378	22365.tif Batch records
	ACTAV 000054379-82	22366.tif Batch records
	ACTAV 00005483-5	22367.tif Batch records
	ACTAV 00005486-90	73063.tif Batch records
	ACTAV 000054259-62	15299.tif Batch records
	ACTAV 000054263-96	15300.tif Batch records
	ACTAV 000054297-304	19448.tif Batch records
	ACTAV 000054305-43	22169.tif Batch records
	ACTAV 000054344-57	22361.tif Batch records
	ACTAV 000054358-85	22362.tif Batch records
	ACTAV 000054386-431	22363.tif Batch records
	ACTAV 000054332-77	22364.tif Batch records
	ACTAV 000054378	22365.tif Batch records
Batch 70836	ACTAV 000056781-8	10932.tif Batch records
	ACTAV 000056789-05	10933.tif Batch records
	ACTAV 000056806-19	10934.tif Batch records
	ACTAV 000056820-33	10935.tif Batch records
	ACTAV 000056834-48	10936.tif Batch records
	ACTAV 000056849-66	10937.tif Batch records
	ACTAV 000056867-77	10938.tif Batch records

	ACTAV 000056878-82	10939.tif Batch records
	ACTAV 000056883-90	10940.tif Batch records
	ACTAV 000056891-96	10941.tif Batch records
	ACTAV 000056897-900	10942.tif Batch records
	ACTAV 000056901-4	10943.tif Batch records
	ACTAV 000056905-6	10944.tif Batch records
	ACTAV 000056907-19	10945.tif Batch records
	ACTAV 000056920-30	10946.tif Batch records
	ACTAV 000056931-4	10947.tif Batch records
	ACTAV 000056935	10948.tif Batch records
	ACTAV 000056936-44	15611.tif Batch records
	ACTAV 000056945-56	15612.tif Batch records
	ACTAV 000056957-69	15613.tif Batch records
	ACTAV 000056970-74	15614.tif Batch records
	ACTAV 000056975-8	15615.tif Batch records
	ACTAV 000056979-7012	15616.tif Batch records
	ACTAV 000057013	15617.tif Batch records
	ACTAV 000057014-20	22193.tif Batch records
	ACTAV 000057021	22194.tif Batch records
	ACTAV 000057022-49	22195.tif Batch records
	ACTAV 000057050-53	22197.tif Batch records
	ACTAV 000057054-81	22198.tif Batch records
	ACTAV 000057082-5	22200.tif Batch records
	ACTAV 000057086-138	22964.tif Batch records
Batch 70925	ACTAV 000057139-46	9071.tif Batch records
	ACTAV 000057147-63	9072.tif Batch records
	ACTAV 000057164-75	9073.tif Batch records
	ACTAV 000057176-91	9074.tif Batch records
	ACTAV 000057192-207	9075.tif Batch records
	ACTAV 000057208-27	9076.tif Batch records
	ACTAV 000057228-41	9077.tif Batch records
	ACTAV 000057242-7	9078.tif Batch records
	ACTAV 000057248-51	9079.tif Batch records
	ACTAV 000057252-7	9080.tif Batch records
	ACTAV 000057258-63	9081.tif Batch records
	ACTAV 000057264-8	9082.tif Batch records
	ACTAV 000057269-72	9083.tif Batch records
	ACTAV 000057273-4	9084.tif Batch records
	ACTAV 000057275-80	9085.tif Batch records
	ACTAV 000057281-2	9086.tif Batch records
	ACTAV 000057283-92	9087.tif Batch records
	ACTAV 000057294-309	9088.tif Batch records
	ACTAV 000057310	9089.tif Batch records
	ACTAV 000057311	9090.tif Batch records

	ACTAV 000057312	9091.tif Batch records
	ACTAV 000057313-6	9092.tif Batch records
	ACTAV 000057317-24	15322.tif Batch records
	ACTAV 000057325-34	15323.tif Batch records
	ACTAV 000057335-42	15324.tif Batch records
	ACTAV 000057343-7	15325.tif Batch records
	ACTAV 000057348-52	15326.tif Batch records
	ACTAV 000057353-6	15327.tif Batch records
	ACTAV 000057357-90	15328.tif Batch records
	ACTAV 000057391	15329.tif Batch records
	ACTAV 000057392-7	18231.tif Batch records
	ACTAV 000057398-401	22383.tif Batch records
	ACTAV 000057402-4	22384.tif Batch records
	ACTAV 000057405-6	22386.tif Batch records
	ACTAV 000057407	22387.tif Batch records
	ACTAV 000057408-17	22388.tif Batch records
	ACTAV 000057418	22389.tif Batch records
	ACTAV 000057419	22390.tif Batch records
	ACTAV 000057420-63	22394.tif Batch records
	ACTAV 000057464-5	22399.tif Batch records
	ACTAV 000057466	41549.tif Batch records
Batch 60777	ACTAV 000020406-9	7410.tif Batch records
	ACTAV 000020410-26	7411.tif Batch records
	ACTAV 000020427-32	14951.tif Batch records
	ACTAV 000020666-7	25781.tif Batch records
Batch 60994	ACTAV 000024355-9	7532.tif Batch records
	ACTAV 000024360-76	7533.tif Batch records
	ACTAV 000024377	7534.tif Batch records
	ACTAV 000024438-43	7541.tif Batch records
	ACTAV 000024493-502	15012.tif Batch records

CD: Selected Standard Operating Procedures (Actavis Totowa) (Martha Bennett)		
Title	**Bates #**	**Description (SOPs)**
455917	ACTAV 000063065-74	AR-018
455929	ACTAV 000063170-3	PKG-002
455930	ACTAV 000063174-7	PKG-003
455931	ACTAV 000063178-83	PKG-004
455932	ACTAV 000063184-6	PKG-005
455941	ACTAV 000063220-3	PRD-001
455942	ACTAV 000063224-7	PRD-002
455946	ACTAV 000063238-41	PRD006
455958	ACTAV 000063281-8	PRD-022
455950	ACTAV 000063294-9	PRD-024

455981	ACTAV 000063336-73	PRD-062
455983	ACTAV 000063374-8	PRD-063
455986	ACTAV 000063381-5	PRD-065
455988	ACTAV 000063393-5	PRD-073
455989	ACTAV 000063398-401	PRD-076
455993	ACTAV 000063402-4	PRD-077
455994	ACTAV 000063416-22	PRD-084
455996	ACTAV 000063423-6	PRD-085
456004	ACTAV 000063431-3	PRD-087
456010	ACTAV 000063458-60	PRD-106
456011	ACTAV 000063472-5	PRD-117
456012	ACTAV 000063476-9	PRD-118
456026	ACTAV 000063480-83	PRD-119
456027	ACTAV 000063527-31	PRD-145
456030	ACTAV 000063532-4	PRD-147
456032	ACTAV 000063542-4	PRD-150
456048	ACTAV 000063548-52	PRD-154
456069	ACTAV 000063606-11	PRD-186
456092	ACTAV 000063713-6	PRD-219
456095	ACTAV 000063803-7	PRD-247
456108	ACTAV 000063812-4	PRD-250
456116	ACTAV 000063867-70	PRD-270
456118	ACTAV 000063900-3	QA-003
456119	ACTAV 000063909-11	QA-015
456121	ACTAV 000063912-5	QA-016
456122	ACTAV 000063922-6	QA-019
456129	ACTAV 000063927-34	QA-020
456131	ACTAV 000063958-60	QA-033
456134	ACTAV 000063964-71	QA-042
456146	ACTAV 000063985-90	QA-045
456147	ACTAV 000064039-41	QA-064
456149	ACTAV 000064042-8	QA-065
456170	ACTAV 000064053-62	QC-123
456184	ACTAV 000064220-6	QC-029
456206	ACTAV 000064313-31	QC-059
456254	ACTAV 000064435-42	QC-106
456271	ACTAV 000064733-6	QC-155L
456282	ACTAV 000064852-8	QC-171
456284	ACTAV 000064932-3	RA-007
456294	ACTAV 000064940-6	RA-021
456307	ACTAV 000065016-21	SOP-0014
456308	ACTAV 000065090-3	SOP-0030
456310	ACTAV 000065094-100	SOP-0033
456311	ACTAV 000065105-12	SOP-0033
456312	ACTAV 000065113-21	SOP-0034

456318	ACTAV 000065122-25	SOP-0035
456323	ACTAV 000065156-9	SOP-0043
456328	ACTAV 000065174-83	SOP-0048
456329	ACTAV 000065206-16	SOP-0055
456336	ACTAV 000065217-27	SOP-0056
456337	ACTAV 000065254-8	SOP-0063
456343	ACTAV 000065259-65	SOP-0064
456346	ACTAV 000065296-9	SOP-0070
456350	ACTAV 000065313-7	SOP-0074
456353	ACTAV 000065331-8	SOP-0080
456354	ACTAV 000065353-7	SOP-0084
584864	ACTAV 000065358-61	SOP-0085
584866	ACTAV 000065391-4	SOP-0079

CD: Annual Reports 2003-2007 Part I of II		
Title	**Bates #**	**Description**
		Digitek Annual Reports 2003-2007

CD: Annual Reports 2003-2007 Part II of II		
Title	**Bates #**	**Description**
		Digitek Annual Reports 2003-2007

CD: In re: Digitek Litigation Bitler & Dowling Transcripts and Recall Package		
Title	**Bates #**	**Description**
41561	ACTAV 000028178-222	Recall package
Bitler, Daniel depo		Deposition w/exhibits
Downling, Richard depo		Deposition w/exhibits

CD: In re: Digitek Litigation Bitler & Dowling Transcripts and Recall Package		
Title	**Bates #**	**Description**
	ACTAV 000005658-86	2003
	ACTAV 000006027-41	2004
	ACTAV 000006146-200	2005
	ACTAV 000006437-83	2006
	ACTAV 000006509-6541	2007

	None	2008
	ACTAV 000002576-622	Investigation
	None	Recall Firm Press Release

CD: Annual Data reviews 2003-2008; Bitler Rpt; Recall Notice; July 2009 FDA Statement		
Title	**Bates #**	**Description**
Digitek Annual Data Reviews 2003-2008		
Bitler Report		
Recall Notice		
July 2009 FDA Statement		

CD: FDA Documents 12/2009		
Title	**Bates #**	**Description**
		From notebooks with tabs

CD: In Re: Digitek Batch Records 701848, 80226 and 80228, 474 Test Results 448892 and 454866		
Title	**Bates #**	**Description**
80226		Batch records
11375	11375	Batch records
11377	11377	Batch records
11379	11379	Batch records
11380	11380	Batch records
11381	11381	Batch records
11382	11382	Batch records
11383	11383	Batch records
11384	11384	Batch records
11385	11385	Batch records
11386	11386	Batch records
11387	11387	Batch records
11388	11388	Batch records
11389	11389	Batch records
11390	11390	Batch records
11391	11391	Batch records
11392	11392	Batch records
11393	11393	Batch records

11394	11394	Batch records
11395	11395	Batch records
11396	11396	Batch records
11397	11397	Batch records
11398	11398	Batch records
11399	11399	Batch records
11400	11400	Batch records
11401	11401	Batch records
11402	11402	Batch records
11403	11403	Batch records
11404	11404	Batch records
15388	ACTAV 001883966-8	Batch records
16105	ACTAV 001885081-6	Batch records
16106	ACTAV 001885087-99	Batch records
16107	ACTAV 001885100-4	Batch records
19551	19551	Batch records
22707	22707	Batch records
22709	22709	Batch records
22710	22710	Batch records
22711	22711	Batch records
22712	22712	Batch records
22713	22713	Batch records
22714	22714	Batch records
22715	22715	Batch records
22903	ACTAV 000029968-30024	Batch records
22924	ACTAV 000003022-3101	Batch records
22952	ACTAV 000061373-427	Batch records
22980	22980	Batch records
77039	77039	Batch records
77040	77040	Batch records
77042	77042	Batch records
77044	77044	Batch records
77045	77045	Batch records
77048	77048	Batch records
77049	77049	Batch records
77052	77052	Batch records
77053	77053	Batch records
77054	77054	Batch records
77055	77055	Batch records
77056	77056	Batch records
77057	77057	Batch records
000292567	ACTAV 000292567	Batch records
0001442391	ACTAV 0001442391	Batch records

80228		
11427	11427	Batch records
11428	11428	Batch records
11429	11429	Batch records
11430	11430	Batch records
11431	11431	Batch records
11432	11432	Batch records
11433	11433	Batch records
11435	11435	Batch records
11436	11436	Batch records
11437	11437	Batch records
11438	11438	Batch records
11439	11439	Batch records
11440	11440	Batch records
11441	11441	Batch records
11442	11442	Batch records
11443	11443	Batch records
11444	11444	Batch records
11445	11445	Batch records
16133	16133	Batch records
16134	16134	Batch records
16135	16135	Batch records
22721	22721	Batch records
22728	22728	Batch records
22729	22729	Batch records
22732	22732	Batch records
22733	22733	Batch records
22735	22735	Batch records
22962	22962	Batch records
22985	22985	Batch records
75252	75252	Batch records
77082	77082	Batch records
77083	77083	Batch records
77084	77084	Batch records
77085	77085	Batch records
77087	77087	Batch records
77089	77089	Batch records
77090	77090	Batch records
77092	77092	Batch records
77100	77100	Batch records
84683	84683	Batch records
343825	343825	Batch records
437164	437164	Batch records
493948	493948	Batch records
2416000	2416000	Batch records

ACTAV 001374256	ACTAV 001374256	Batch records
ACTAV 001883966	ACTAV 001883966-8	Batch records
ACTAV 001885188	ACTAV 001885188-95	Batch records
ACTAV 001885250	ACTAV 001885250-55	Batch records
ACTAV 001885256	ACTAV 001885256-61	Batch records
ACTAV 001885262	ACTAV 001885262-69	Batch records
ACTAV 001900529	ACTAV 001900529	Batch records
448892		
00000001-62	NONE	FDA sample records
454866		
00000063-119	NONE	FDA sample records
70148		Batch Records
8548	8548	Batch Records
8549	8549	Batch Records
8550	8550	Batch Records
8551	8551	Batch Records
8552	8552	Batch Records
8553	8553	Batch Records
8554	8554	Batch Records
8555	8555	Batch Records
8556	ACTAV 001897236-252	Batch Records
8557	8557	Batch Records
8558	8558	Batch Records
8559	8559	Batch Records
8560	8560	Batch Records
8561	8561	Batch Records
8562	8562	Batch Records
8563	8563	Batch Records
14501	ACTAV 001883117-143	Batch Records
14502	ACTAV 001883135-8	Batch Records
14503	ACTAV 001883139-51	Batch Records
14504	ACTAV 001883152	Batch Records
15127	ACTAV 001883930-47	Batch Records
15128	ACTAV 001883948-51	Batch Records
15129	ACTAV 001883952-64	Batch Records
15131	15131	Batch Records
15132	15132	Batch Records
19436	ACTAV 000030886-903	Batch Records
19449	ACTAV 000037280-99	Batch Records
21720	21720	Batch Records
21721	21721	Batch Records
21722	21722	Batch Records

21723	ACTAV 000041909-49	Batch Records
21724	ACTAV 000041950-72	Batch Records
21725	21725	Batch Records
21727	21727	Batch Records
21728	21728	Batch Records
21729	ACTAV 000037360-400	Batch Records
21730	21730	Batch Records
21731	ACTAV 000037401-6	Batch Records
21732	ACTAV 000041973	Batch Records
21733	21733	Batch Records
21734	21734	Batch Records
21736	21736	Batch Records
21737	21737	Batch Records
38552	ACTAV 000013235-511	Batch Records
39578	ACTAV 000038601-43	Batch Records
73315	73315	Batch Records
75264	75264	Batch Records
208124	208124	Batch Records
Potentially Privileged		
16091	16091	Batch reject form
19438	19438	Investigation log
1603430	1603430	Finished product release

CD: Digitek Litigation 6-18-2010 ANDA (Production Version)		
Title	**Bates #**	**Description**
ANDA I-III	ACTAV 000000709-2111	

CD: Digitek Litigation Stability Studies – recalled Batches 05/25/2010		
Title	**Bates #**	**Description**
Batch 60319	ACTAV 000006929-7146	
Batch 70023	ACTAV 000029867-966	
Batch 70078	ACTAV 000032708-3255	
	ACTAV 000650898-902	
	ACTAV 000977125-131	
Batch 70081	ACTAV 000033217-255	
Batch 70174	ACTAV 000650982-4	
Batch 70670	ACTAV 000049348-93	

Batch 80133	ACTAV 001690549-64	
Batch 71049-71050-710501	ACTAV 001690580-604	
Finished Product Stability Test report 146	ACTAV 000065607-9	

CD: Digitek Litigation 6-18-2010 ANDA (Production Version)		
Title	**Bates #**	**Description**
ANDA I-III	ACTAV 000000709-2111	

CD: Digitek Litigation (8) Folders containing… 3rd party testing; pre-recall docs; tabs 6-11 plaintiff's potential deposition		
Title	**Bates #**	**Description**
3rd party testing	UDLL 000011679-769	Celsis documents
		Digitek chart recalled batches
		Gibraltar documents
	74521	QRS Protocol
	ACTAV 001867195-224	Quantic Docs
		Radtke depo transcript
2008 pre-recall MedWatch & product complaints		2008 Pre-recall MedWatch Rpts recd 3-10-10
		2008 Pre-recall MedWatch Complaint Forms recv 3-10-10
Tab 6	Plaintiffs ex 107	
	Plaintiffs ex 125	
	Plaintiffs ex 138	
Tab 7	Plaintiffs ex 128	Double thick tablet Field Alert
Tab 8	ACTAV 000028850-29378	Response to Oct 2006 inspection
	75911	
	144053	
	538415	
	72795	
Tab 9	ACTAV 000165623-30	Blend failure
	ACTAV 001423286-8	
Tab 10	Plaintiffs ex 129	
Tab 11	Plaintiffs ex 141	

	Plaintiffs ex 142	
	Plaintiffs ex 144	
	Plaintiffs ex 145	